IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

In re Testosterone Replacement Therapy	**)**	
Products Liability Litigation Coordinated	**)**	**Case No. 14 C 1748**
Pretrial Proceedings	**)**	**MDL No. 2545**
	)	
(This order applies to all cases)	**)**	

CASE MANAGEMENT ORDER NO. 48
(Rulings on AbbVie's motion for summary judgment on "off-label" marketing claims and motion to exclude testimony and AbbVie's motions to exclude opinions of Dr. Steven Woloshin and Dr. Curt Furberg (dkt. 1727, 1731 & 1746))

MATTHEW F. KENNELLY, District Judge:

Plaintiffs in this multidistrict litigation proceeding allege that they have suffered either arterial cardiovascular injuries or injuries related to blood clots in the veins (venous thromboembolisms, or VTEs) as a result of taking prescription testosterone replacement therapy (TRT) drugs. Defendants AbbVie Inc., Abbott Laboratories, AbbVie Products LLC, and Unimed Pharmaceuticals, LLC (collectively, AbbVie) manufacture AndroGel, one of the TRT drugs at issue in this litigation. Seven plaintiffs who have sued AbbVie have been selected to proceed with bellwether trials beginning June 2017.

Each bellwether plaintiff—Edward Cribbs, Cecile Frost, Jeffrey Konrad, Jesse Mitchell, Arthur Myers, Robert Nolte, and Robert Rowley—alleges that AndroGel caused him to suffer either a cardiovascular or VTE injury. AbbVie has filed three motions for summary judgment, each one addressing different claims or issues. In this opinion, the Court addresses AbbVie's motion for summary judgment on what it calls plaintiffs' "off-label marketing claims"—more precisely, plaintiffs' claims of fraud,

negligent misrepresentation, violation of consumer protection statutes, breach of express warranty, breach of implied warranty of merchantability, and negligence. The Court also addresses AbbVie's motions to exclude the testimony of certain experts retained by plaintiffs, specifically, Drs. David A. Kessler, Peggy Pence, Steven Woloshin, David J. Handelsman, Hossein Ardehali, and Curt Furberg.

Background

The Court takes the following factual background from the parties' briefs and exhibits on summary judgment. Where facts are in dispute, the Court takes them in the light most favorable to plaintiffs, the non-moving parties.

1. Hypogonadism

In men, testosterone is a hormone produced by the Leydig cells in the testicles. Testosterone is the primary androgenic hormone responsible for normal male physical and sexual development.

Male hypogonadism is an absence or deficiency of testosterone resulting from a pathological condition of the testes, the hypothalamus, or the pituitary. It is generally characterized as "primary" or "secondary" hypogonadism. Primary hypogonadism is the result of testicular failure to produce adequate levels of testosterone. Secondary hypogonadism results from a disorder of the pituitary gland or the hypothalamus. Hypogonadism in adult males can result in decreased sexual interest and desire, erectile dysfunction, benign breast enlargement, decreased muscular strength, sparse body hair, and reduced bone mass. Primary and secondary hypogonadism are sometimes called "classical" hypogonadism.

As men age, it is normal for their testosterone levels to decline. This is not a

result of any pathology, and it has not generally been considered to be a medical condition that requires treatment. The plaintiffs in this litigation contend that AbbVie (along with other pharmaceutical manufacturers) engaged in a concerted marketing campaign to convince physicians and the public that reduced testosterone levels resulting from age—what has been referred to as "low T;" "andropause;" or age-related hypogonadism—is a medical condition that is appropriately treated with testosterone replacement therapy drugs.

2. FDA approval of AndroGel

Testosterone replacement therapy has been used to treat hypogonadism for more than 75 years. In April 1996, AbbVie's predecessor submitted to the FDA an Investigational New Drug Application (INDA) for a topical testosterone gel intended for use in treating primary and/or secondary hypogonadism in men. The INDA proposed clinical trials designed to demonstrate the safety and efficacy of AbbVie's T-gel product to raise testosterone levels to that of a male with healthy and functioning testes. In April 1999, AbbVie submitted a New Drug Application for its T-gel product, which was named AndroGel 1%. The FDA approved AndroGel 1% on February 28, 2000. The FDA approved AndroGel 1% as "safe and effective for use as recommended in the agreed upon labeling text." Defs.' Ex. 30.

On September 15, 2006, AbbVie submitted an INDA for AndroGel 1.62%. The FDA's determination to approve AndroGel 1.62% was based on a two-phase, 364-day controlled clinical study. AbbVie later submitted an NDA for AndroGel 1.62%. On April 29, 2011, the FDA approved AndroGel 1.62% for "replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone" as

described on the approved product label. Defs.' Ex. 32 at ABBVIE-FST01906236.

3. AndroGel's indicated uses

When the FDA approves a drug, the drug is deemed effective and safe for certain medical conditions. The use for which a drug has been approved is referred to as an "indication." A label for an approved drug—including both the physical label and the package inserts for physicians and patients—may indicate use only for the approved indications. A drug manufacturer may not include a new indication on its labels without receiving prior approval from the FDA.

In February 2000, when the FDA first approved AndroGel 1%, the indication on the label read as follows:

> AndroGel™ is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone:
>
> 1. Primary hypogonadism (congenital or acquired) – testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone levels and gonadotropins (FSH, LH) above the normal range.
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> 2. Hypogonadotropic hypogonadism (congenital or acquired) – idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum levels but have gonadotropins in the normal or low range.

Defs.' Ex. 35 at E35-003.

In April 2011, when AndroGel 1.62% was approved by the FDA, this language was modified as follows (with new wording in bold):

> AndroGel™ is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone:
>
> 1. Primary hypogonadism (congenital or acquired) – testicular failure due to **conditions such as** cryptorchidism, bilateral torsion, orchitis, vanishing

testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone **concentrations** and gonadotropins (**follicle-stimulating hormone** [FSH], **luteinizing hormone** [LH]) above the normal range.

2. Hypogonadotropic hypogonadism (congenital or acquired) – idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum levels but have gonadotropins in the normal or low range.

Defs.' Ex. 36 at E36-003.

In 2006, AbbVie requested an indication for a third type of hypogonadism: "hypogonadism due to multiple defects in the hypothalamus-pituitary-gonadal (HPG) axis in men – e.g. DAX-1 mutations, hemochromatosis, sickle disease, glucocorticoid, ***age***, alcoholism, HIV-infected, or chronic opioid use." Pls.' Ex. 17 at Vol. 1, p. 0003 (emphasis added). AbbVie referred to this type of hypogonadism as "combined primary and secondary hypogonadism" and/or mixed hypogonadism. Pls.' Ex. 45 at AbbVie-FST06104728. In effect, AbbVie sought an indication for what it now calls non-classical hypogonadism. The FDA rejected AbbVie's proposed third indication, stating that "[t]he indications for AndroGel 1.62% will be the same as for all previously approved products in this class. No specific claims for the treatment of age-related hypogonadism ('andropause') will be allowed in the labeling." Pls.' Ex.18 at ABBVIEFST00009098.

4. AndroGel promotional materials

On March 21, 2000, AbbVie submitted its planned introductory promotional materials for AndroGel 1% to the FDA for advisory review and comment prior to disseminating them. The FDA provided AbbVie with its comments on April 12, 2000. The FDA took issue with AbbVie's claims that AndroGel was an appropriate treatment

for age-related hypogonadism. The proposed materials stated that AndroGel delivers "[n]ormal 24-hour serum testosterone levels—[r]egardless of hypogonadal causes (primary, secondary, age-associated)." Defs.' Ex. 42 at E42-004. The materials also claimed that "[g]reater than 60% of men over 65 have free testosterone levels below normal values of men aged 30-35." *Id*. The FDA said that this language should be removed from the proposed promotional materials because "[c]laims and representations that suggest AndroGel is indicated for men with 'age-associated' hypogonadism or 'andropause' are misleading." *Id*. The FDA explained that AndroGel is only "indicated in males with primary hypogonadism or hypogonadotropic hypogonadism." *Id*. The FDA also took issue with AbbVie's claim that AndroGel will "increase muscle strength and stamina," commenting that the claim was misleading because it "has not been demonstrated by substantial evidence." *Id*. The FDA noted that its "comments on a particular claim or representation should be applied to all future materials that contain similar claims and representations." *Id*. at E42-002.

Following the FDA's initial approval of AndroGel 1.0%, AbbVie launched a comprehensive advertising campaign for AndroGel. AbbVie's strategy was to "[p]ursue age-related hypogonadism market expansion"; "[e]ducate and motivate physicians to treat low T"; and "[e]ducate patients about the symptoms of and benefits of treating low testosterone." Pls.' Ex. 37. AbbVie's strategy for advertising AndroGel to primary care physicians, specifically, was to "sell market expansion first and AndroGel second." Pls.' Ex. 38. To accomplish this, AbbVie directed its pharmaceutical representatives to talk "in terms of low testosterone and not hypogonadism" because it found that primary care physicians did not respond well to the term "hypogonadism." *Id*.

This same strategy is reflected in AbbVie's approach towards its direct-to-consumer advertisements. AbbVie's direct consumer marketing of AndroGel during this period generally consisted of branded and unbranded advertising. AbbVie needed the FDA's prior authorization before disseminating a new advertisement for AndroGel. Generally, the FDA sought to keep AbbVie's branded advertisements of AndroGel consistent with the product's approved label. For example, in June 2003, AbbVie submitted to the FDA a proposed television advertisement featuring a man discussing symptoms of low testosterone. In the proposed advertisement, a man states, "I hadn't been feeling like myself for a while . . . I was tired, felt down and my sex drive was in neutral. My doctor said any one of these symptoms, among others, could be a sign of low testosterone." Defs.' Ex. 48 at E48-008. While the man makes this statement, the language "LOW TESTOSTERONE (hypogonadism)" is superimposed on the image in bold text. In a later shot of the advertisement, the man states that "over 4 million men have low testosterone and . . . while AndroGel might not be right for everyone . . . your doctor will know . . . if it's right for you." *Id*. In that same frame, the language "NOT FOR EVERYONE" and "INDIVIDUAL RESULTS MAY VARY" are superimposed on the image. *Id*. at E48-009. According to an AbbVie report, the FDA took no issue with this advertisement because the agency believed the advertisement did not "differ substantially from the material currently in use." Defs.' Ex. 49.

Unbranded advertisements do not require FDA review because the FDA considers unbranded advertisements educational rather than promotional. AbbVie's unbranded advertisements focused on "disease awareness" and made no product-specific claims. Specifically, AbbVie launched a disease awareness advertising

campaign for men with low testosterone or "Low T." AbbVie distributed direct-to-consumer advertisements through unbranded websites, third parties, and television advertisements, encouraging aging men to ask their healthcare professionals to test them for low testosterone or "Low T." For example, in 2001, AbbVie released an unbranded advertisement that appeared in question-and-answer format. The advertisement stated:

> Q: Should I just accept my low testosterone as a natural part of getting old?
>
> A: Experts have determined that testosterone replacement therapy (TRT) may help counter some of the more serious debilitating, effects of aging. In addition to its known role in aiding sexual desire and function, TRT may also help patients maintain bone mineral density (which is important for avoiding bone fractures), increase their amount of muscle, and decrease body fat. There is also evidence to suggest that TRT can help improve mood. If you're hypogonadal, TRT may help you maintain your health and preserve your lifestyle.

Pls.' Ex. 40.

In 2005, AbbVie distributed a direct-to-consumer print advertisement showing a coffee cup and an energy bar with the following text superimposed on the image: "For nearly 8 million men, no amount of coffee can replace the energy they've lost. If fatigue, depressed mood, or low sex drive is part of your daily grind, you have low testosterone (Low T)." Defs.' Ex. 54 at ABBVIE-FST00383450. One page of the advertisement invites consumers to answer a 10-question survey to identify if they suffer from low T. The page bears the caption, "Could your thirst for energy be caused by Low T?" *Id*. The advertisement suggests TRT as treatment for low T, claiming that TRT "can raise testosterone levels, which may improve your energy, mood, and sex drive." *Id*.

In 2009, an AbbVie unbranded commercial encouraged men who felt they had

less energy to investigate an unbranded website, IsItLowT.com, to consider whether they suffered from low T. Pls.' Ex. 1 (Kessler Report) ¶ 251 & n.235. The advertisement stated:

> Millions of men 45 and older just don't feel like they used to. Are you one of them? Remember when you had more energy for 18 holes with your buddies? More passion for the one you love? More fun with your family and friends? It could be a treatable condition called low testosterone or Low T.

Id.

AbbVie's unbranded commercials, slide kits for physicians, and other promotional material during the relevant period encouraged physicians and patients to investigate testosterone replacement for aging males. AbbVie's advertisements suggested that having testosterone levels below 300 ng/dL is indicative that a patient has age-related hypogonadism or age-related low testosterone.

Prescriptions for TRTs overall rose after the introduction of AndroGel 1%.

5. Risks associated with AndroGel

On February 9, 2015, the FDA directed AbbVie to change its labels for AndroGel 1% and AndroGel 1.62% because it had become aware "of the risk of major adverse cardiovascular outcomes associated with testosterone replacement therapy." Pls.' Ex. 80 at ABBVIE-FST03767438. The FDA directed AbbVie to remove "idiopathic" from AndroGel's indication for hypogonadotropic hypogonadism, which stated, "idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation." Pls.' Ex. 79 at ABBVIE-FST02620706; Pls.' Ex. 80 at ABBVIE-FST03767441. The FDA also directed AbbVie to add language indicating that AndroGel had not been determined to be safe and

effective for age-related hypogonadism. For example, under AndroGel's "indications and usage" section, the FDA directed AbbVie to add the language that, "[s]afety and efficacy of AndroGel [1% and 1.62%] in men with age-related hypogonadism have not been established" and that "[a]ge-related hypogonadism refers to men with serum testosterone concentrations below the normal range for no apparent reason other than age, and who experience signs and symptoms of aging that overlap with those of hypogonadism." Pls.' Ex. 79 at ABBVIE-FST02620705; Pls.' Ex. 80 at ABBVIE-FST03767442.

In March 2015, the FDA issued a drug safety communication for testosterone products and cautioned medical practitioners against prescribing the drug for conditions for which it was not indicated:

> The U.S. Food and Drug Administration (FDA) cautions that prescription testosterone products are approved only for men who have low testosterone levels caused by certain medical conditions. **The benefit and safety of these medications have not been established for the treatment of low testosterone levels due to aging, even if a man's symptoms seem related to low testosterone.** We are requiring that the manufacturers of all approved prescription testosterone products change their labeling to clarify the approved uses of these medications. We are also requiring these manufacturers to add information to the labeling about a possible increased risk of heart attacks and strokes in patients taking testosterone. Health care professionals should prescribe testosterone therapy only for men with low testosterone levels caused by certain medical conditions and confirmed by laboratory tests.
>
> **Testosterone is FDA-approved as replacement therapy only for men who have low testosterone levels due to disorders of the testicles, pituitary gland, or brain that cause a condition called hypogonadism.** Examples of these disorders include failure of the testicles to produce testosterone because of genetic problems, or damage from chemotherapy or infection. However, **FDA has become aware that testosterone is being used extensively in attempts to relieve symptoms in men who have low testosterone for no apparent reason other than aging.** The benefits and safety of this use have not been established.

Pls.' Ex. 6 (emphasis added).

Discussion

AbbVie has moved for summary judgment on what it refers to as plaintiffs' off-label marketing claims.[1] Summary judgment is appropriate if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56 (a); *Wedemeyer v. CSX Transp., Inc.*, 850 F.3d 889, 894 (7th Cir. 2017). In making this determination, the Court construes all facts and draws reasonable inferences in favor of the nonmoving party. *Id*.

A. "Off-label marketing" claims

AbbVie argues that it is entitled to summary judgment on what it calls plaintiffs' off-label marketing claims because 1) they are repackaged failure to warn claims; 2) they constitute an improper attempt to enforce the Federal Food, Drug, and Cosmetic Act (FDCA) via private lawsuits; 3) plaintiffs cannot show that AbbVie made any false or misleading statements in its promotional material; 4) they cannot establish reliance on any statements made in off-label marketing of AndroGel; 5) they cannot show that AbbVie's off-label marketing was the proximate cause of their injuries; 6) they cannot support their claims for breach of express warranty because there is no evidence that AbbVie made any specific affirmations in its advertisements; 7) plaintiff Mitchell's express and implied warranty claims are barred by Oregon Revised Statutes § 72.6070(3); 8) plaintiff Rowley's consumer protection claim is barred by the Utah Consumer Sales Practices Act; 9) plaintiffs are not entitled to punitive damages; and 10)

[1] Plaintiff Robert Rowley does not assert claims against AbbVie arising from off-label marketing of AndroGel.

plaintiff Cribbs cannot show that he conferred a benefit directly on AbbVie as needed to support his unjust enrichment claim.

1. Failure to warn

AbbVie argues that what it calls plaintiffs' off-label marketing claims involve two types of alleged misrepresentations. The first, AbbVie contends, are alleged misrepresentations that AndroGel was approved for age-related hypogonadism / low T—what AbbVie calls "misbranding misrepresentations." The second, AbbVie contends, are alleged misrepresentations that AndroGel was a safe and effective treatment for age-related hypogonadism / low T—what AbbVie calls "safety misrepresentations." *See* Defs.' Mem. in Supp. of Mot. for Summ. J. on Pls.' Off-Label Claims (Defs.' Mem.) at 30. AbbVie argues that claims of misbranding misrepresentations constitute an improper attempt to enforce the FDCA and are, in any event, unsupported. *See id.* at 31. It argues that claims of safety misrepresentations are "repackaged failure-to-warn claim[s]" that are preempted by federal law and are, in any event, unsupported. *See id.* at 37.

Plaintiffs, however, have not asserted claims for off-label marketing of AndroGel. Rather, they assert claims for intentional and negligent misrepresentation, breach of warranty, and violation of state consumer protection statutes. In these claims, they contend that AbbVie made false statements about AndroGel's efficacy and safety. It may be that these claims involve AbbVie's marketing of AndroGel for non-indicated uses, but that does not mean they are claims "for off-label marketing" of the drug.

In any event, the Court disagrees with AbbVie's contention that these claims represent, in part, a mere relabeling (no pun intended) of plaintiffs' claims alleging

failure to warn. The two are logically distinct, and even if there is overlap in their factual or legal underpinnings, there is nothing that prevents a party from asserting multiple but legally distinct claims that arise from the same events. And finally, even if these claims tracked the failure to warn claims, this would not entitle AbbVie to summary judgment. AbbVie's contention is that the failure to warn claims are deficient for reasons argued in a separate motion for summary judgment, and thus any repackaging of those claims fails for the same reasons. But the Court has separately denied AbbVie's motion for summary judgment on plaintiffs' failure to warn claims, and the same reasoning would warrant denying summary judgment on the supposedly "repackaged" claims.

For the remainder of this opinion, in referring to plaintiff's misrepresentation and warranty-based claims, the Court will call them the "marketing claims" for ease of reference.

2. Preemption / private enforcement of FDCA

AbbVie asserts that it is entitled to summary judgment on plaintiffs' marketing claims that concern "misbranding" because these claims constitute an improper attempt to privately enforce FDA regulations that prohibit drug manufacturers from promoting off-label uses of their drugs. AbbVie notes that plaintiffs use the term "misbranding" throughout their complaint and make allegations that AbbVie's marketing of AndroGel violated FDA regulations.

Regulations under the FDCA prohibit a drug manufacturer from promoting off-label uses of its prescription drugs. *See* 21 C.F.R. § 202.1(e)(6). And dissemination of an advertisement not in compliance with FDA regulations causes a drug to be "misbranded" in violation of the FDCA. 21 C.F.R. § 202.1(j)(3); 21 U.S.C. § 352(n). But

the statute states that "all . . . proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a).

Thus what is really at issue here is a question of federal preemption. State law claims that seek only to enforce FDA regulations are impliedly preempted. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001). In *Buckman*, plaintiffs brought a fraud claim based on a misrepresentation the defendant allegedly made during the FDA approval process for its medical device—essentially a claim of fraud on the FDA. The Court noted that "the federal statutory scheme amply empower the FDA to punish and deter fraud against the [agency], and . . . this authority is used by the [agency] to achieve a somewhat delicate balance of statutory objectives." *Id.* at 348. This balance, the Court concluded, "can be skewed by allowing fraud-on-the-FDA claims under state tort law." *Id.* In concluding that the plaintiffs' fraud-on-the-FDA claim was preempted, however, the Court distinguished cases in which the plaintiff's claim arises from traditional state tort law principles and not "solely from the violation of FDCA requirements." *Id.* at 352. Such claims are not preempted, even if the "state-law causes of actions . . . parallel federal safety requirements." *Id.* at 353. In other words, the Court in *Buckman* "specifically distinguished . . . 'fraud-on-the-agency' claims, i.e., claims not related to a field of law that states had traditionally occupied." *Bausch v. Stryker Corp.*, 630 F.3d 546, 557 (7th Cir. 2010). *See also Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1235 (9th Cir. 2013) (the Court in *Buckman* held that the plaintiffs' claim "was impliedly preempted because it sought to enforce an exclusively federal requirement and was not grounded in traditional state tort law.").

In the present cases, plaintiffs' marketing claims are not impliedly preempted by

the FDCA or under *Buckman*, because the claims are grounded in traditional state law principles of liability, such as negligence, failure to warn, strict product liability, and fraud that predate the relevant FDCA requirements. The claims do not depend on violations of requirements or prohibitions imposed by the FDCA. *McDaniel v. Upsher-Smith Pharm*., Inc., No. 216CV02604JPMCGC, 2017 WL 657778, at *5 (W.D. Tenn. Jan. 26, 2017) ("Plaintiff's claim of fraud and deceit is not expressly or impliedly preempted [because] [s]tate laws traditionally prohibit fraud and deceit in advertising and marketing as well."); *Arvizu v. Medtronic Inc.*, 41 F. Supp. 3d 783, 791 (D. Ariz. 2014) ("But Plaintiffs do not allege misrepresentations or omissions based on the FDA approved label. Rather, they allege that Defendants 'fraudulently concealed and misrepresented information' about the off-label uses of the Infuse Device. These claims lie parallel to federal requirements.") (applying the MDA and Arizona law); *Alton v. Medtronic, Inc*., 970 F. Supp. 2d 1069, 1098 (D. Or. 2013) (finding that claims based on allegations of misrepresentation "are sufficient to state an actionable claim under the Oregon common law of fraud, independently of the FDCA or of any other federal law."); *Ramirez v. Medtronic Inc.*, 961 F. Supp. 2d 977, 994-95 (D. Ariz. 2013) ("The state law claims here exists independent of federal law. Put another way, all things being equal, [plaintiff] could bring a claim against [defendant] for knowingly concealing information in off-label promotion even if off-label promotion was legal under federal law.").

As plaintiffs contend and as the Court has noted, plaintiffs' off-label claims do not depend on a finding that AbbVie violated the FDCA or FDA regulations. For example, a reasonable jury could find AbbVie liable for making misrepresentations about the safety and efficacy of AndroGel for treating age-related hypogonadism or for making

misrepresentations about the indications for which the FDA approved AndroGel. And although plaintiffs' complaints make reference to regulations regarding misbranding, they do so in the context of establishing the standard of care that they contend AbbVie breached, and to help establish AbbVie's intent and motive in connection with its marketing of AndroGel. *See, e.g.,* Fourth Am. Master Compl. ¶¶ 494-500. The fact that plaintiffs cannot assert claims to enforce the FDCA's prohibitions or requirements does not preclude them from, for example, introducing evidence regarding the indications for which the FDA approved AndroGel. "*Buckman* does not mean plaintiffs cannot bring state law claims based on conduct that violates the FDCA." *Eidson v. Medtronic, Inc*., 981 F. Supp. 2d 868, 880-81 (N.D. Cal. 2013).

3. False or misleading statements

AbbVie contends that no reasonable jury could find that it made false or misleading representations in its marketing, particularly in its "Low T" marketing campaign. It argues that one of AndroGel's indicated uses as approved by the FDA was to treat "idiopathic" hypogonadism, and it contends this includes age-related hypogonadism. A reasonable jury could find, however, that this is not the case. As indicated earlier, there is evidence that the FDA repeatedly rejected requests or attempts by AbbVie to include age-related hypogonadism as an indicated use. And the agency also commented, with its reviewed AbbVie's initial proposed promotional materials, that claims suggesting AndroGel is indicated for men with age-associated hypogonadism or "andropause" were misleading. A reasonable jury could find that AbbVie made false or misleading representations when it marketed AndroGel with statements to the effect that it is a safe and effective treatment for age-related "low T."

AbbVie also contends that the FDA approved its unbranded advertising material. It evidently submitted to the FDA a direct-to-consumer print advertisement referring to hypogonadism as low T and including symptoms associated with age-related hypogonadism. The ad shows a coffee cup and an energy bar with the following text superimposed on the image: "For nearly 8 million men, no amount of coffee can replace the energy they've lost. If fatigue, depressed mood, or low sex drive is part of your daily grind, you have low testosterone (low T)." Defs.' Ex. 54 at ABBVIE-FST00383450. The FDA did not comment, but the agency's charge does not require review or approval of unbranded advertisements of this type. AbbVie offers no support, and the Court is aware of none, for the proposition that the FDA's silence indicates its approval of the ad or similar ads.

Finally, AbbVie argues that it used in its unbranded ads only language that the FDA had approved for branded advertising. But context matters, and the Court is unpersuaded that AbbVie can bootstrap the FDA's okaying of language for one purpose into a determination that, as a matter of law, the company's use of the same language for another purpose and in a different context was not false or misleading.

4. Reliance / causation

AbbVie argues that plaintiffs cannot establish the necessary reliance on any false or misleading statements in its advertising. Assuming plaintiffs are, as AbbVie contends, required to prove that their prescribing physicians relied on the misstatements—a proposition for which AbbVie provides only scant support, *see* Defs.'

Mem. at 42-43[2]—a reasonable jury could make the requisite finding in plaintiffs' favor.

The state laws governing the bellwether trial cases use some variation of the definition of reliance found in the Restatement of Torts: "In order to justify recovery, the recipient of a misrepresentation must rely upon the truth of the misrepresentation itself, and his reliance upon its truth must be a substantial factor in inducing him to refrain from action." Restatement (2d) of Torts § 548. A plaintiff need not show that his (or, if AbbVie is right, his physician's) reliance was the sole or even the predominant influence; rather, "[i]t is enough that the representation has played a substantial part, and so has been a substantial factor, in influencing his decision." *Whiteley v. Philip Morris Inc.*, 117 Cal. App. 4th 635, 678, 11 Cal. Rptr. 3d 807, 843 (2004) (internal citations and quotation marks omitted). "Except in the rare case where the undisputed facts leave no room for a reasonable difference of opinion, the question of whether a plaintiff's reliance is justified is a question of fact." *Parrish v. Wells Fargo Bank, N.A*., No. D070686, 2017 WL 411052, at *6 (Cal. Ct. App. Jan. 31, 2017) (internal quotation marks omitted).

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[2] Though the Court need not decide the point definitively at this juncture, it has serious doubt regarding whether the learned intermediary doctrine, which most commonly applied in connection with failure to warn claims, also applies to the types of claims addressed in this ruling. Under the doctrine, a manufacturer or supplier of a prescription drug has no legal duty to warn a consumer of the drug's dangerous propensities, so long as it provides adequate warnings to the prescribing physician. *See, e.g., Carlin v. Superior Court*, 13 Cal. 4th 1104, 1126, 920 P.2d 1347, 1360 (1996). But here AbbVie directed its marketing not only to physicians but also to the general public. If false or misleading representations in the direct-to-consumer advertising influenced an individual to request the drug in the first instance or to decide to take it once prescribed, it is not all that easy to see why the learned intermediary doctrine should govern in a way that would bar his claim. It would seem that if a misrepresentation was a substantial factor vis-à-vis *either* the decision by a physician to prescribe the drug *or* the decision by a plaintiff to request or take it, that should be enough. The Court likely will require further briefing on this topic in connection with the upcoming trials.

The evidence is sufficient to support a reasonable finding by a jury that each of the prescribing physicians relied on AbbVie's alleged misrepresentations regarding the safety and efficacy of testosterone replacement therapy in general and AndroGel specifically in prescribing the drug for the plaintiffs. Each of the physicians testified regarding "low T" marketing efforts by AbbVie sales representatives, and a reasonable jury could find in each instance that AbbVie's marketing of the drug for age-related hypogonadism or other non-indicated uses was a substantial factor in the prescribing decision. Some of them testified that they did not base their decisions *entirely* on information from sales representatives, but as noted earlier, that is not the issue—"substantial factor" is the standard, not total and complete reliance to the exclusion of everything else. And this same analysis requires overruling AbbVie's argument regarding causation.

5. Express warranty

AbbVie argues that plaintiffs' breach of express warranty claims fail because there is no evidence that the company made any specific affirmations in its marketing. AbbVie also singles out plaintiff Konrad, arguing that his express warranty claim fails because Tennessee law requires actual reliance and the evidence would not permit a finding that Konrad relied on any express warranty. AbbVie has not explained why for breach of express warranty should be treated differently under Tennessee law than under the law of the other states at issue. The Court has previously ruled that, to state a claim for breach of express warranty in every state at issue, plaintiffs must point to a specific affirmation or promise on which the plaintiffs relied. *In re Testosterone Replacement Therapy Prod. Liab. Litig*., No. 14 C 1748, 2014 WL 7365872, at *8 (N.D.

Ill. Dec. 23, 2014). Indeed, the Court initially dismissed plaintiffs' express warranty claims because they failed to specify affirmations or promises from AbbVie on which they relied. Now, after having amended their complaint to cure the pleading defect, plaintiffs have presented evidence sufficient for a reasonable jury to find that AbbVie, through its marketing, specifically affirmed and represented to consumers that 1) "low T" was a condition in need of treatment and 2) AndroGel was a safe and an effective treatment for age-related reduced testosterone levels.

To summarize, plaintiffs have presented evidence sufficient for a jury to find that AbbVie attempted to create and market "low T" as, in effect, a disease requiring treatment. An example of this is AbbVie's advertisement that states, "[i[f fatigue, depressed mood, or low sex drive is part of your daily grind, you may have low testosterone (Low T)." Defs.' Ex. 54 at ABBVIE-FST00383450. Plaintiffs have also provided evidence sufficient to find that AbbVie represented that AndroGel was a safe, effective treatment for treating "low T." By way of example, one unbranded advertisement for AbbVie states, "Testosterone replacement therapy can raise testosterone levels, which may improve your energy, mood, and sex drive." *Id*. at 3. This sort of advertising prompted Nolte, for example, to ask his doctor to prescribe AndroGel, because he believed it would "cure" him and make him "whole again." Pls.' Ex. 64 (Nolte Dep.) at 123:12-13. Likewise, Frost stated that AbbVie's advertisements "made [AndroGel] sound like it was a miracle cure for testosterone problems . . . ." Pls.' Ex. 72 (Frost Dep.) at 196:9-20. Finally, plaintiffs have also provided evidence of specific affirmations that AbbVie representatives made to plaintiffs' prescribing physicians, including that AndroGel was a safe, effective treatment for age-related

hypogonadism. AbbVie is not entitled to summary judgment on the express warranty claims of the bellwether plaintiffs other than Mitchell, which the Court addresses below.

6. Implied warranty

AbbVie argues that Mitchell's express and implied warranty claims are barred because he failed to notify AbbVie of the warranty breach prior to filing his lawsuit, as allegedly required by section 72.6070(3) of the Oregon Revised Statutes. Mitchell argues that section 72.6070(3) does not govern because it applies to claims of nonconforming goods initially accepted by the purchaser "presumably to provide an opportunity to cure." Pls.' Resp. to Defs.' Mot. for Summ. J. (Pls.' Resp.) at 69.

Section 72.6070(3) provides when a tender of goods has been accepted, "[t]he buyer must within a reasonable time after the buyer discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." District courts in Oregon have interpreted the "notice requirement of § 72.6070(3) to apply in warranty actions for personal injuries resulting from the purchase of a consumer product, including an action against a contraceptive drug maker." *Parkinson v. Novartis Pharm. Corp*., 5 F. Supp. 3d 1265, 1276 (D. Or. 2014) (internal quotation marks omitted). In *Allen v. G.D. Searle & Co*., 708 F. Supp. 1142 (D. Or. 1989), the court said that it "has not located any Oregon decision holding that notice is no longer required in a warranty action for personal injuries resulting from the purchase of a consumer product." *Id.* at 1160. The court noted that the Supreme Court of Oregon stated that notice is an essential element of a claim for breach of warranty. *Id*. (citing *Redfield v. Mead, Johnson & Co*., 266 Or. 273, 284, 512 P.2d 776, 781 (1973)). The court concluded that, "[i]n the absence of any authority for abolishing the notice

requirement, and in the absence of any evidence that [the plaintiff] gave notice of her express or implied warranty claims, this court must rule that [the plaintiff] has not established an essential element of her warranty claims." *Allen*, 708 F. Supp. at 1160; *see also, e.g*., *Simonsen v. Ford Motor Co.*, 196 Or. App. 460, 463, 102 P.3d 710, 713 (2004) (acknowledging notice requirement in a product liability case); *Canady v. Ortho-McNeil Pharm., Inc.*, No. 3:11 OE 40011, 2014 WL 4930675, at *5 (N.D. Ohio Oct. 1, 2014) (applying Or. Rev. Stat. § 72.6070); *In re ConAgra Foods Inc*., 908 F. Supp. 2d 1090, 1111 (C.D. Cal. 2012) (same).

Mitchell contends that section 30.900 of the Oregon Revised Statutes abolishes the notice requirement because it "sets forth statutory product liability claims supersedes the U.C.C. statute." Pls.' Resp. at 69. But the case in which Mitchell relies, *Phelps v. Wyeth, Inc.*, 857 F. Supp. 1114, 1123 (D. Or. 2012), makes no mention of superseding the notice requirement in section 72.6070(3) or overruling the Oregon Supreme Court's decision in *Redfield*.

The Court grants summary judgment in favor of defendants on Mitchell's express warranty claim due to the absence of prior notice required by Or. Rev. Stat. § 72.6070(3). Mitchell's implied warranty claim, however, may proceed; none of the authorities cited above apply section 72.6070(3) to implied warranty claims.

7. Consumer protection

AbbVie argues that Rowley's consumer protection claim should be dismissed because the Utah Consumer Sales Practices Act does not permit claims predicated on personal injury. It is true that Utah Code Ann. § 13-11-22(1)(c) states that the statute does not apply to a "claim for personal injury or death or claim for damage to property

other than the property that is the subject of the consumer transaction." But Rowley does not seek personal injury-type damages on his consumer fraud claim; rather, he seeks to recover economic losses, such as the costs of purchasing AndroGel. *See* Pls.' Resp. at 69. This would appear to be a proper form of recovery, so the Court declines to grant summary judgment for AbbVie on Rowley's consumer protection statutory claim.

8. Punitive damages

AbbVie contends that Arizona, Oregon, and Utah law bars punitive damages in pharmaceutical products liability actions where the product was manufactured and labeled in accordance with terms approved by the FDA or is generally recognized as safe and effective under FDA regulations. AbbVie also argues that it is entitled to summary judgment on the claims from the states at issue that do allow for punitive damages—California, North Carolina, and Tennessee—because plaintiffs cannot prove that AbbVie engaged in fraud. Plaintiffs contend that Illinois law governs punitive damages in these cases because AbbVie is domiciled in Illinois. The Court agrees with plaintiffs for the reasons discussed in its separate ruling regarding plaintiffs' failure to warn and products liability claims.

Under Illinois law, "punitive damages may be awarded when the defendant acted with fraud, actual malice, deliberate violence or oppression, or when the defendant acted willfully, or with such gross negligence as to indicate a wanton disregard for the rights of others." *Ross v. Black & Decker, Inc*., 977 F.2d 1178, 1187 (7th Cir. 1992) (internal quotation marks omitted). Factors to be considered in determining whether the conduct of a defendant in a products liability case warrants imposition of punitive

damages include the defendant's knowledge of a defect in its product and its corresponding knowledge that the defect is likely to cause injury, and its failure to take action to avoid the potential for injury arising from the defect. *Dewick v. Maytag Corp*., 296 F. Supp. 2d 905, 907 (N.D. Ill. 2003). Thus, plaintiffs need only present evidence that would permit a reasonable jury to find that AbbVie knew that AndroGel was not a safe and effective treatment for age-related low testosterone and yet marketed it as if it was.

Plaintiffs here have presented evidence sufficient to permit a reasonable jury to find that that AbbVie had knowledge that its advertisements contained false or misleading statements. AbbVie was told on several occasions that AndroGel was not an appropriate treatment for age-related low testosterone. For example, the FDA removed language in AndroGel's initial promotional material that attempted to relay the message that AndroGel was a safe, effective treatment for age-related low testosterone. The FDA said that this language should be removed because "[c]laims and representations that suggest AndroGel is indicated for men with 'age-associated' hypogonadism or 'andropause' are misleading." Defs.' Ex. 42 at E42-004. AbbVie nonetheless launched an advertising campaign to arguably create and then capture the age-related hypogonadism market for its product. There is evidence that it adopted a strategy to "[p]ursue age-related hypogonadism market expansion;" "[e]ducate and motivate physicians to treat low T;" and "[e]ducate patients about the symptoms of and benefits of treating low testosterone." Pls.' Ex. 37. AbbVie's strategy for advertising AndroGel to primary care physicians, specifically, was to "sell market expansion first and AndroGel second." Pls.' Ex. 38. To accomplish this, AbbVie directed its

pharmaceutical representatives to talk "in terms of low testosterone and not hypogonadism" because it found that primary care physicians did not respond well to the term "hypogonadism." *Id*. AbbVie also launched a "disease awareness" advertising campaign for men with low testosterone levels. It distributed direct-to-consumer advertisements through unbranded websites, third parties, and television advertisements, encouraging aging men to request that their healthcare professionals test them for "low T."

This and other evidence offered by plaintiffs would permit a reasonable jury to find that AbbVie acted willfully and wantonly, thus permitting an award of punitive damages.

10. Unjust Enrichment

The Court has separately ruled on AbbVie's request for summary judgment on Cribbs's claim of unjust enrichment.

B. Motions to exclude expert testimony

AbbVie has also moved to exclude the testimony of several experts that plaintiffs have retained to support their marketing claims: Drs. David A. Kessler, Peggy Pence, Steven Woloshin, David J. Handelsman, Hossein Ardehali, and Curt Furberg.

The admission of expert testimony is governed by Federal Rule of Evidence 702 and the principles set forth in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993). Rule 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; and

(d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

A district court plays the role of gatekeeper in determining whether proposed expert testimony meets the standards of Rule 702. *Daubert*, 509 U.S. at 597. To fulfill this role, the Court must determine whether 1) the expert is qualified to give the opinion she is offering; 2) the testimony is based on a reliable methodology; and 3) whether the testimony will assist the trier of fact in understanding the evidence or determining a fact at issue in the case. *Cummins v. Lyle Indus.*, 93 F.3d 362, 368 (7th Cir. 1996).

In ascertaining whether an expert is qualified, the Court asks "not whether an expert witness is qualified in general, but whether his qualifications provide a foundation for him to answer a specific question." *Gayton v. McCoy*, 593 F.3d 610, 617 (7th Cir. 2010). In making this determination, the Court is to "consider a proposed expert's full range of practical experience as well as academic or technical training." *Smith v. Ford Motor Co*., 215 F.3d 713, 718 (7th Cir. 2000).

Concerning reliability, the Supreme Court provided in *Daubert* a non-exhaustive list of factors for determining whether scientific testimony is sufficiently reliable to be admitted into evidence. *Daubert*, 509 U.S. at 593-94. Relevant factors for assessing the reliability of an expert's methods include "(1) whether the scientific theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether a particular technique has a

known potential rate of error; and (4) whether the theory or technique is generally accepted in the relevant scientific community." *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 431 (7th Cir. 2013).

The thrust of the *Daubert* inquiry is to ensure "that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). The inquiry is necessarily a flexible one because the determination of whether an expert's methods are reliable "is an individualized test whose relevant factors will depend on the type of expertise at issue in a given case." *Smith*, 215 F.3d at 720. For example, though peer reviewed publications can be relevant in assessing an expert's reliability, the "lack of peer review will rarely, if ever, be the single dispositive factor that determines the reliability of expert testimony." *Id*. An expert may draw upon a number of sources to form a reliable opinion, including from his own professional knowledge, skill, and expertise, so long as they are relevant to the subject on which the expert seeks to offer his testimony. *See*, *e.g., Walker v. Soo Line R.R. Co*., 208 F.3d 581, 591 (7th Cir. 2000) ("Rule 702 specifically contemplates the admission of testimony by experts whose knowledge is based on experience."). Indeed, experts commonly rely on their professional experience to "offer opinion testimony regarding the standard of care and generally-accepted industry standards." *Cage v. City of Chicago*, 979 F. Supp. 2d 787, 803 (N.D. Ill. 2013) (citing *WH Smith Hotel Servs., Inc. v. Wendy's Int'l, Inc*., 25 F.3d 422, 429 (7th Cir. 1994)).

In addition to being reliable, the expert's testimony must assist the trier of fact.

This is essentially a relevance inquiry. "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Porter v. Whitehall Labs., Inc*., 9 F.3d 607, 613 (7th Cir. 1993) (internal quotation marks omitted). If an expert's testimony is helpful to the jury, it is admissible even if it "cover[s] matters that are within the average juror's comprehension." *United States v. Hall*, 93 F.3d 1337, 1342 (7th Cir. 1996). Testimony that would be unhelpful to a jury may be barred under Rule 702 and can be excluded under Federal Rule of Evidence 403. *See Thompson v. City of Chicago*, 472 F.3d 444, 457 (7th Cir. 2006).

Expert testimony that effectively usurps the role of the jury is generally considered to be unhelpful. As this Court has stated, "testimony that does little more than tell the jury what result to reach is unhelpful and thus inadmissible." *Dahlin v. Evangelical Child & Family Agency*, No. 01 C 1182, 2002 WL 31834881, at *3 (N.D. Ill. Dec. 18, 2002) (internal quotation marks omitted). For example, expert testimony "about legal issues on which the judge will instruct the jury" is typically inadmissible because it does not assist the finder of fact in making its ultimate decision. *United States v. Sinclair*, 74 F.3d 753, 758 n.1 (7th Cir. 1996); *see, e.g.*, *Good Shepherd Manor Found., Inc. v. City of Momence*, 323 F.3d 557, 564 (7th Cir. 2003). Similarly, "testimony regarding intent . . . is even more likely to be unhelpful to the trier of fact" because the expert merely draws "inferences from the evidence" that the jury could draw equally well. *Dahlin*, No. 01 C 1182, 2002 WL 31834881, at *3 (internal quotation marks omitted).

Expert testimony may also be excluded under Rule 403. Rule 403 provides that "relevant evidence may be excluded if its probative value is substantially outweighed by

the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Fed. R. Evid. 403. Evidence is "unfairly prejudicial in the context of Rule 403 if it will induce the jury to decide the case on an improper basis, commonly an emotional one, rather than on the evidence presented." *Common v. City of Chicago*, 661 F.3d 940, 947 (7th Cir. 2011) (internal quotation marks omitted).

The proponent of expert testimony bears the burden of establishing, by a preponderance of the evidence, that the testimony satisfies *Daubert*'s standards and is otherwise admissible. *Lewis v. CITGO Petroleum Corp.*, 561 F.3d 698, 705 (7th Cir. 2009). When determining whether the proponent of expert testimony has met that burden, however, a court must be mindful that "[a] *Daubert* inquiry is not designed to have the district judge take the place of the jury to decide ultimate issue of credibility and accuracy." *Lapsley v. Xtek, Inc.*, 689 F.3d 802, 805 (7th Cir. 2012). If the credibility or accuracy of an expert opinion is in question, the proper remedy is not exclusion of the testimony, but rather testing the opinion before the jury using the traditional tools of "vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof." *Daubert*, 509 U.S. at 596.

1. Dr. David A. Kessler

AbbVie has moved to exclude the testimony of plaintiffs' expert Dr. David Kessler, contending that his opinions are unreliable, improper, and unfairly prejudicial. Specifically, AbbVie argues that (1) Dr. Kessler is not qualified to testify about "off-label" marketing or the risks associated with it; (2) his opinions are improper because he bases them on an unreliable methodology; (3) he offers improper testimony regarding

the motives, intent, and thought processes of AbbVie and the FDA; (4) he offers inadmissible legal conclusions regarding FDA law and policy; (5) his testimony includes an improper factual narrative; and (6) his opinions are unfairly prejudicial, confusing, and misleading to the jury.

First, AbbVie argues that Dr. Kessler is not qualified to offer opinions on pharmaceutical marketing practices because he has no education or training in that field; he has never evaluated or analyzed a pharmaceutical marketing campaign as part of academic research; and he has never authored or commissioned a pharmaceutical marketing report or worked in pharmaceutical marketing.

Contrary to AbbVie's contention, Dr. Kessler is amply qualified to offer his opinions on AbbVie's' marketing of AndroGel, including whether it marketed and promoted the drug for non-indicated, off-label uses. Dr. Kessler is a former Commissioner of the FDA, a position that involved the regulation of marketing by drug manufacturers; he has taught food and drug law; he has testified before Congress on food, drug, and consumer protection issues; he has authored numerous publications on federal regulation of food, drugs, and medical devices; he advises companies on the standards of care within the pharmaceutical and medical device industry; and he is a senior advisor to a private equity firm that owns pharmaceutical and biomedical companies. He is certainly qualified to render opinions regarding whether a drug manufacturer is marketing its product for off-label uses.

Second, AbbVie argues that Dr. Kessler is not qualified to testify on whether there is a causal relationship between AndroGel and the increased risks of harm to patients. Dr. Kessler has conceded as much, but plaintiffs are not offering his testimony

on the issue of causation. Rather, Dr. Kessler opines that studies linking TRT to certain increased health risks should have led AbbVie conduct further investigation regarding the link. These opinions pertain to regulatory and pharmaceutical industry standards, which are plainly within Dr. Kessler's area of expertise. It is appropriate for Dr. Kessler, in offering these opinions, to rely on the testimony of plaintiffs' causation experts regarding what the studies showed and the risks posed by TRT.

Third, AbbVie argues that Dr. Kessler's opinions are unreliable because they are based only on his personal experience as opposed to an independent, objective, or scientific methodology. However, the Court has already noted that Rule 702 permits an expert to draw on his professional experience in informing his opinion. *See Walker*, 208 F.3d at 591. And Dr. Kessler currently advises pharmaceutical companies on how best to comply with FDA regulations and industry standards. When he was Commissioner of the FDA, Dr. Kessler had to assess whether a company's practices and promotional materials complied with FDA regulations. His professional experience provides him with a wealth of knowledge that he appropriately may draw upon in forming his opinions for this case.

Fourth, AbbVie contends that Dr. Kessler's testimony on the rules and regulations governing FDA drug approval and off-label marketing, whether the FDA approved AndroGel for certain uses, what federal regulation permitted AbbVie to say about AndroGel in its marketing, and whether its purposed off-label marketing of AndroGel exposed patients to increased risk all constitute legal conclusions that are barred by Rule 702. On the last of these points, it does not appear that Dr. Kessler purports to offer his own independent views regarding exposure to risk; he relies on

AbbVie's labeling (specifically, its references to health risks) and defers to opinions to be offered by other experts. *See* Kessler Report ¶¶ 448-49, 452-53.

There is no *per se* rule barring expert testimony on matters of law. The field of FDA regulation of pharmaceutical products and marketing is highly complex, and a jury reasonably requires assistance to understand it. *See, e.g., In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig.*, No. 3:09-MD-02100-DRH, 2011 WL 6302287, at *12 (S.D. Ill. Dec. 16, 2011) (admitting Dr. Kessler's testimony in a related area). And as the Court has discussed, plaintiffs' claims are based on state law doctrines such as negligence, failure to warn, strict products liability, breach of warranty, and fraud. The ultimate conclusions a jury will have to draw are rooted in state law, not federal law. And Dr. Kessler's testimony does not cover the ultimate issues that the jury will decide; rather, it concerns off-label marketing and FDA regulations. This testimony is neither irrelevant, otherwise improper, or unfairly prejudicial or confusing.[3] That said, the Court agrees with AbbVie that Dr. Kessler may not appropriately testify about the role of state tort liability vis-à-vis the federal regulatory scheme, as this is a purely legal determination on which the Court has made rulings and will instruct the jury and on which it is therefore inappropriate to provide testimony. (This does not appear to be a particularly significant aspect of Dr. Kessler's anticipated testimony. *See* Kessler Report ¶ 71 ("[T]he two systems of state consumer protection and federal food and drug regulation operate in a complementary but independent manner.").)

[3] Limiting instructions may be necessary, but that is a matter that can be addressed later upon an appropriate request.

Fifth, AbbVie argues that Dr. Kessler's testimony is improper because he "simply regurgitate[s] evidence that could be presented directly to the jury." Defs.' Mem. at 56. This includes his anticipated testimony on the history of AndroGel's promotional materials and its dealings with the FDA. AbbVie contends that Dr. Kessler's testimony amounts to an improper factual narrative with a "spin" that requires no specialized knowledge. It contends that this amounts to improper advocacy that would invade the "fact-finding province of the jury." *Id.*

The Court disagrees. Dr. Kessler's testimony will assist the jury in determining its ultimate conclusions, and it presents no danger of invading the jury's province. Moreover, to the extent he is summarizing voluminous records and materials, as appears to be the case, this aspect of his testimony is properly admitted under Federal Rule of Evidence 1006 as well as Rule 702 in the sense that he is identifying what he, given his background and expertise, considers to be the most salient aspects of those voluminous materials. *See, e.g., In re Yasmin*, 2011 WL 6302287, at *13. AbbVie will have a full and fair opportunity to address any claims of incompleteness or undue emphasis during cross-examination and presentation of contrary evidence. *See id.* (citing *United States v. Pree*, 408 F.3d 855, 871 (7th Cir. 2005)).

Sixth, AbbVie argues that Dr. Kessler improperly seeks to offer testimony on AbbVie's knowledge, motivations, and intent. It takes particular issue with Dr. Kessler's opinion regarding the "intended use" of AndroGel. Specifically, Dr. Kessler opines that AbbVie's "intended use for AndroGel included treatment for patients with low testosterone independent of the medical conditions for which the drug was approved." Kessler Report ¶ 313; *see also, e.g., id.* ¶¶ 466-68. The testimony surrounding this

particular terminology is properly admissible. Dr. Kessler evaluates AbbVie's marketing materials and internal memoranda to assess whether and to what extent it was targeting persons with conditions outside of AndroGel's indicated use. He also offers a framework by which the jury can assess what AbbVie intended via its marketing. But although Dr. Kessler may walk up to this line, he may not cross it; he cannot offer an opinion or conclusion about what AbbVie intended, as that is a function properly reserved to the jury.

Finally, AbbVie argues that Dr. Kessler's expert testimony should be excluded because it is unfairly prejudicial. Specifically, it suggests that based on his background, plaintiffs will be able to portray him as the ultimate authority in his field. The Court is somewhat perplexed by this objection; AbbVie seems to be arguing that Dr. Kessler is *too* qualified to testify. Regardless, the Court overrules the objection. In the Court's experience, if an expert comes across as a know-it-all, he tends not to be believed, and cross-examination is a sufficient check. That aside, AbbVie may raise this point if appropriate before closing argument in addressing what plaintiffs' counsel may and may not say in arguing Dr. Kessler's level of authoritativeness.

2. Dr. Peggy Pence

Next, AbbVie seeks to exclude the testimony of Dr. Peggy Pence. AbbVie takes issue with Dr. Pence's opinions that AbbVie improperly marketed AndroGel for off-label uses, violated the FDA's regulations against misbranding, and violated industry standards of care in marketing of AndroGel for off-label uses.

AbbVie argues that certain of Dr. Pence's opinions are unreliable. Specifically, it argues that Dr. Pence's testimony regarding an "industry standard of care" is a product

of nothing other than her own speculation. Defs.' Mem. at 58. But in making this argument, AbbVie cites only to a single heading in Dr. Pence's report that uses this term; it does not reference any opinions rendered in the body of the report or during her deposition.[4] Without more, the argument is too bare-boned for consideration. Perfunctory arguments are forfeited. That said, it appears that Dr. Pence's 40-plus years of experience in research and development of pharmaceutical products and her concurrent 25 years of experience in consulting on testing, clinical trials, and FDA regulatory matters gives her a sufficient basis to testify regarding industry standards in these areas.

AbbVie also argues that Dr. Pence's opinion that the company contravened FDA regulations on misbranding constitutes an improper legal conclusion. The Court overrules this argument for the reasons discussed with regard to the parallel contention regarding Dr. Kessler. The Court likewise overrules AbbVie's argument that Dr. Pence's report contains an improper factual narrative, for the reasons discussed with regard to Dr. Kessler. AbbVie will have a full and fair opportunity at trial to cross-examine Dr. Pence on the accuracy and completeness of her summary of relevant events and to make appropriate objections under Rule 403 regarding the use of pejorative terminology.

AbbVie further argues that Dr. Pence's testimony is improper to the extent she intends to testify regarding the FDA's reasons for acting or failing to act, specifically, her opinion that the FDA did not issue AbbVie a warning for its off-label promotion of

[4] To be fair, plaintiffs' response, in which they argue that Dr. Pence has a sufficient basis to testify about industry standards, likewise does not cite to the record.

AndroGel because the FDA "lacked the resources to enforce its own rules." Defs.' Mem. at 60. The Court agrees that Dr. Pence lacks a sufficient basis to testify regarding why the FDA acted (or failed to act) and that this particular opinion would be inadmissible in any event, either as speculative, unhelpful to the jury, or unfairly prejudicial under Rule 403.

Finally, AbbVie makes an objection to the testimony of Dr. Pence that it made with respect to Dr. Kessler—plaintiffs will portray her as the ultimate authority, and this is unfairly prejudicial. The Court overrules this argument for the reasons discussed with regard to Dr. Kessler.

3. Dr. Steven Woloshin

AbbVie seeks to exclude the testimony of Dr. Steven Woloshin, arguing that he is not qualified to render opinions on the propriety or effect of drug advertising or what he calls "disease mongering" because he has no degree in marketing and is not well-versed in federal regulations on pharmaceutical marketing. AbbVie also argues that Dr. Woloshin's testimony is unreliable and unfairly prejudicial.

Dr. Woloshin has the requisite knowledge, skill, and experience to offer his opinions, with the limitations noted below. He uses the term "disease mongering" to describe efforts to convince people that they are sick and need a medical treatment for this sickness. He is a professor at Geisel School of Medicine at Dartmouth, New Hampshire and co-directs the Dartmouth Institute for Health Policy and Clinical Practices. Besides being board-certified in internal medicine, he is a widely published author, including in peer reviewed journals regarding over-diagnosis and over-promotion of drugs. He is sufficiently qualified to render his opinions; AbbVie's arguments about

his level of expertise go to the weight to be given his testimony, not its admissibility.

AbbVie also argues that Dr. Woloshin has not identified a reliable, scientific basis for his opinion that AbbVie engaged in "disease mongering" in relation to its "Is it Low-T?" campaign. But nothing in *Daubert* or its progeny requires an expert to have or create a scientific test before he can give his opinion on a subject that he has studied for more than a decade. *See Hill v. Brass Eagle, Inc.*, No. 15 C 368, 2016 WL 4505170, at *6 (N.D. Ill. Aug. 29, 2016) (Kennelly, J.). Though Dr. Woloshin conceded a test might be conceived, there is no basis for determining that such a test would be any more reliable or accurate than the review he conducted of AbbVie' marketing and promotional plans. Dr. Woloshin identifies whether a company is engaged in "disease mongering" by reviewing the company's internal documents, FDA materials, peer-reviewed journal articles, and expert reports, and that is what he did here. In addition, Dr. Woloshin's prior opinions using similar methodology have been tested through his own work on randomized, controlled experiments that have evaluated drug advertising, as well as various other forms of communications designed to convey drug information to consumers. The Court concludes that the methodology Dr. Woloshin employed is sufficiently reliable to meet the requirements of *Daubert* and Rule 702.

AbbVie also argues that Dr. Woloshin's opinions effectively amount to speculation about AbbVie's motives and intentions in marketing and promoting AndroGel. But Dr. Woloshin is not offering testimony suggesting that he knows AbbVie's intent. Instead, he relies largely on AbbVie's internal marketing materials to illustrate that they track the strategies for "disease mongering" that he has researched, observed, and written about (including in a peer-reviewed editorial published in the

Journal of the American Medical Association's JAMA-Internal Medicine publication before he was approached or retained as an expert in this proceeding). The strategies he has identified are to lower the bar for diagnosis of the purported "disease," raise the stakes of not being diagnosed so that people want to get tested and treated, and pitch the evidence about the purported benefits of treatment in such a way that failure to be diagnosed and treated might threaten one's health. Dr. Woloshin has analyzed AbbVie's marketing practices with these strategies in mind to opine on whether it engaged in behavior indicative of a company employing a disease mongering strategy. Like Dr. Kessler, because Dr. Woloshin is offering the jury a framework by which to analyze AbbVie's off-label marketing practices, not testimony purporting to describe AbbVie's actual intent, his testimony on the matter is permissible.

Finally, AbbVie argues that some of the terms Dr. Woloshin uses, such as "disease mongering," "predatory practice," and "unconscionable" are inflammatory and should be barred under Rule 403 as unfairly prejudicial. The Court agrees. Testimony that AbbVie acted in an "unconscionable" way is a value judgment and a conclusion that the jury can draw—or not draw—without being told to draw it. "Disease mongering" may be a catchy term, but if it is a term of art, it is one that Dr. Woloshin apparently created himself, and it carries a pejorative connotation that, again, strays beyond what an expert may appropriately say. He will have to use a less loaded phrase when addressing this topic during his testimony (unless, of course, AbbVie opens the door). The same is true of testimony calling a particular practice "predatory." That term may have an accepted meaning in the antitrust context, but this is not an antitrust case. Like "unconscionable," it represents in this context a value judgment, as opposed to a point

on which an expert appropriately may opine.

4. Dr. David Handelsman

AbbVie seeks to exclude the testimony of plaintiffs' expert Dr. David Handelsman. Dr. Handelsman discusses in his report why having an age-related low testosterone level is not an indication for testosterone replacement therapy; he (like Dr. Woloshin) concludes that AbbVie engaged in "disease mongering" by promoting TRT for non-pathological hypogonadism; and he offers opinions regarding the dangers of testosterone supplementation.

AbbVie contends that Dr. Handelsman, who lives and works in Australia, is not qualified to offer opinions regarding "disease mongering" or AbbVie's marketing strategies. AbbVie points out that that he has never authored or commissioned a report on pharmaceutical marketing, has no training in pharmaceutical sales or marketing, and has no clinical experience in the United States.

Dr. Handelsman is a medical doctor and medical school professor who specializes in reproductive endocrinology and andrology. He is a highly-published and highly-cited author worldwide on testosterone and androgens. The relevance of his knowledge and expertise regarding endocrinology and andrology is not diminished by the fact that he has not practiced in the United States; there is no basis to believe that the study or science of these topics is any different in Australia as compared with the United States.

Given his background and experience, Dr. Handelsman is sufficiently qualified to offer most of the opinions addressed in his report. For example, his expertise as an endocrinologist qualifies him to opine regarding the rarity of idiopathic hypogonadism

and whether age-related hypogonadism is considered a form of idiopathic hypogonadism. For the same reason, he is sufficiently qualified to testify regarding the accuracy of statements about "low T" in AbbVie's marketing materials and whether these materials focused on conditions for which the drug was indicated or rather on other conditions like age-related low testosterone levels.

Dr. Handelsman is not qualified, however, to opine about whether the evidence indicates that AbbVie was engaged in "disease mongering;" he has no background and appears not to have done any study or writing in this area. The Court also notes that this particular opinion from Dr. Handelsman likely would be subject to exclusion under Federal Rule of Evidence 403 on the basis of cumulativeness given that plaintiffs intend to elicit the same opinion from Dr. Woloshin.

AbbVie also seeks to exclude certain of Dr. Handelsman's opinions on the basis of unreliability or unfair prejudice. His testimony regarding overprescribing of TRT—that is, for conditions for which it is medically unwarranted—is sufficiently reliable to be admissible, and it is not unfairly prejudicial. Dr. Handelsman examined data regarding the estimated population of men with classical or idiopathic hypogonadism and compared that with data regarding the number of men being treated with TRT, concluding that the latter number far exceeds the likely population of those who have a medical need for TRT.

AbbVie asks to preclude plaintiffs from eliciting opinions from Dr. Handelsman on the cause-and-effect relationship between AbbVie's marketing campaigns for AndroGel and overprescribing. It does not appear, however, that plaintiffs intend to elicit this from Dr. Handelsman (and the Court agrees this is outside his area of expertise). Rather,

this testimony, to the extent it is being offered, will come from Dr. Woloshin.

Finally, Dr. Handelsman may testify regarding the proposition that prescribing TRT for men for whom the drug is not indicated subjects them to increased health risks. That is within the scope of his relevant expertise. The Court notes that plaintiffs have disavowed calling Dr. Handelsman as a causation expert; causation testimony will be elicited from other expert witnesses. The Court also overrules AbbVie's unfair prejudice objection, except to the extent it concerns cumulativeness, an issue the Court will address later.

To be more specific, with reference to the 20-point summary of opinions at the outset of his report, Dr. Handelsman may testify regarding the opinions described in paragraphs 1 through 10. Opinion 11 is likewise admissible, except without the pejorative adjectives "aggressive," "flamboyant," "opportunistic," and "irresponsible," which are precluded for the reasons discussed with regard to Dr. Woloshin's use of similar terminology. Opinions 12 and 13 are a conclusion that AbbVie engaged in disease mongering, which the Court excludes for the reasons discussed. Opinion 14 is admissible to the extent it concerns "extending . . . [the] disease definition ('hypogonadism') to include age-related reductions in circulating testosterone" (etc.), but without the reference to disease mongering. Opinions 15, 16, 17, and 19 are admissible. Opinion 18 is basically a value judgment regarding AbbVie's conduct and is excluded.

5. Dr. Hossein Ardehali

AbbVie seeks to exclude certain testimony by plaintiffs' expert Dr. Hossein Ardehali. Specifically, it challenges two of Dr. Ardehali's opinions:

> The totality of the evidence demonstrates that the administration of exogenous testosterone to middle-aged and older men who are diagnosed with testosterone declines unrelated to classical hypogonadism is dangerous because it increases the risk of coronary artery and cerebrovascular occlusive events (heart attack and stroke). The use of testosterone products in this population for the treatment of non-classical hypogonadism is unapproved.
>
> The promotion and marketing of testosterone therapy in this population of men by AndroGel companies was unreasonable in the absence of adequate safety data, and based on the approved indication for use, and in the presence of a body of evidence which, in its totality, demonstrated that the administration of testosterone was unsafe.

The first of these opinions is also targeted in AbbVie's motion for summary judgment on causation, and the Court has addressed this opinion in its ruling on that motion. Plaintiffs agree that the second opinion, concerning the reasonableness of AbbVie's marketing, is outside the scope of Dr. Ardehali's expertise; they do not intend to offer his testimony on this topic. Thus no further discussion of Dr. Ardehali is necessary.

6. Dr. Curt Furberg

Finally, AbbVie has filed a separate motion to exclude the testimony of plaintiffs' expert Dr. Curt Furberg, whose Rule 26(a)(2) disclosure includes opinions regarding the sufficiency of the clinical trials conducted on AndroGel prior to its approval by the FDA; the effects of AbbVie's marketing; and the content of the AndroGel labels. AbbVie argue that Dr. Furberg lacks sufficient expertise to render these opinions and they are otherwise inadmissible under *Daubert* and Rule 702. In response to the motion, plaintiffs state that they will not be offering Dr. Furberg as an expert on advertising or marketing, so AbbVie' motion is moot to that extent.

Dr. Furberg unquestionably has sufficient expertise to evaluate AbbVie's clinical

trials. He served with the National Heart, Lung, and Blood Institute and eventually became chief of its clinical trials branch; he was director of Wake Forest University School of Medicine's Center for Prevention Research and Biometry; and he was a longtime member of the FDA's Drug Safety and Risk Management Advisory Committee. He has authored or coauthored over 400 articles and 60 book chapters, mainly in the fields of epidemiology and clinical trials, and he has coauthored a textbook regarding clinical trials. The Court could go on, but it need not.

The primary topic of Dr. Furberg's anticipated testimony appears to be the sufficiency and adequacy of the clinical trials that led to the FDA's approval of AndroGel 1% and AndroGel 1.62%. AbbVie's main argument is that plaintiffs are intending to use Dr. Furberg's testimony to contend that the FDA should not have approved AndroGel because the clinical trials were inadequate to demonstrate its safety and efficacy. Plaintiffs say they are not challenging the FDA's approvals or to support a claim of fraud on the FDA, and the Court agrees that plaintiffs cannot advance claims along these lines. But the testimony is properly admissible, in the Court's view, to attempt to show that AbbVie and its predecessors conveyed misleading information to physicians and patients concerning the safety and efficacy of the product. For example, one of Dr. Furberg's opinions is that the studies (and other reports) do not establish AndroGel's efficacy and safety in men with "low T" or "andropause." *See* Defs.' Mot. to Exclude Testimony of Pls.' Expert Dr. Furberg, Ex. 4 (Furberg Report) at 39. This, when considered with other evidence that plaintiffs will offer, is relevant and admissible to assist in establishing, among other things, that AbbVie made false representations regarding AndroGel.

The Court also overrules AbbVie's attack on Dr. Furberg's methodology—more specifically, its contention that he has none. Dr. Furberg's report and deposition sufficiently lay the basis for his critique of the studies in question in a way that has a sufficiently reliable foundation in the relevant literature.

Finally, the Court overrules AbbVie's argument that plaintiffs should be precluded from offering Dr. Furberg's opinion that the labeling on AndroGel reflects that it is indicated only for certain types of hypogonadism, and not for "low T" or "andropause." Dr. Furberg's experience gives him a sufficient basis and background to describe what the labels mean and what they do not mean, a matter on which the jury appropriately may need assistance. This testimony is relevant and admissible regarding a number of the misrepresentation and warranty-based claims advanced by plaintiffs.

Because these are the only opinions that plaintiffs say they will attempt to elicit from Dr. Furberg—in other words, *not* his opinions regarding the propriety or effect of AbbVie's marketing of AndroGel, the Court need not address the other arguments made in AbbVie's motion. The motion [dkt. 1727] is denied for the reasons described.

7. A final comment on expert testimony

The Court has the impression from its review of the motions addressed in this decision that plaintiffs may intend to offer testimony by multiple expert witnesses on particular topics in a given bellwether trial. The Court does not intend to permit this by either side absent a prior showing of good cause. *See* N.D. Ill. LR Form 16.1.4 (final pretrial order form) at 2 n.7 ("Only one F.R. Evid. 702 witness on each subject for each party will be permitted to testify absent good cause shown."); Fed. R. Evid. 403. As the Court explained to counsel at a recent case management conference, if a party

attempts to present duplicative expert testimony without obtaining prior permission, it risks preclusion or striking of the second or following experts on a particular topic. Thus any party intending to present overlapping and potentially duplicative testimony would be well advised to seek guidance before doing so.

Conclusion

For the foregoing reasons, the Court denies defendants' motions to exclude the opinions of Dr. Curt Furberg and Dr. Steven Woloshin [dkt. nos. 1727 & 1731]. The Court also denies defendants' motion for summary judgment on plaintiffs' "off-label marketing" claims and to exclude testimony [dkt. no. 1746], except as to the breach of express warranty claim by plaintiff Mitchell, on which the Court grants summary judgment for defendants, and except as to various items of expert testimony as discussed in the body of this opinion.

MATTHEW F. KENNELLY
United States District Judge

Date: May 8, 2017